

JS 44 (Rev. 12/07) (and rev 1-16-08)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO OF THE FORM.)

I. (a) PLAINTIFFS Richard Mora	DEFENDANTS AstraZeneca Pharmaceuticals, LP, AstraZeneca LP
(b) County of Residence of First Listed Plaintiff Sonoma County, CA (EXCEPT IN U.S. PLAINTIFF CASES)	County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.
(c) Attorney's (Firm Name, Address, and Telephone Number) David C. Andersen The Miller Firm, LLC 108 Railroad Avenue Tel: (540) 672-4224	Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)	III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)																																
<input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	<table border="0" style="width: 100%;"> <tr> <th colspan="2"></th> <th>PTF</th> <th>DEF</th> <th colspan="2"></th> <th>PTF</th> <th>DEF</th> </tr> <tr> <td>Citizen of This State</td> <td><input checked="" type="checkbox"/> 1</td> <td><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td><input type="checkbox"/> 4</td> <td><input type="checkbox"/> 4</td> <td></td> <td></td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td><input type="checkbox"/> 5</td> <td><input checked="" type="checkbox"/> 5</td> <td></td> <td></td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> <td></td> <td></td> </tr> </table>			PTF	DEF			PTF	DEF	Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4			Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5			Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6		
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V. ORIGIN (Place an "X" in One Box Only)	
<input checked="" type="checkbox"/> 1 Original Proceeding <input type="checkbox"/> 2 Removed from State Court <input type="checkbox"/> 3 Remanded from Appellate Court <input type="checkbox"/> 4 Reinstated or Reopened	Transferred from <input type="checkbox"/> 5 another district (specify) <input type="checkbox"/> 6 Multidistrict Litigation <input type="checkbox"/> 7 Judge from Magistrate Judgment

VI. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. 1332 Brief description of cause: Personal Injury, Products Liability, Seroquel MDL
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VII. REQUESTED IN COMPLAINT:	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 <input type="checkbox"/> DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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VIII. RELATED CASE(S) IF ANY	PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE "NOTICE OF RELATED CASE". Seroquel MDL 1769, Middle District of Florida
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IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2) (PLACE AND "X" IN ONE BOX ONLY)	<input checked="" type="checkbox"/> SAN FRANCISCO/OAKLAND <input type="checkbox"/> SAN JOSE
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DATE 5-29-08	SIGNATURE OF ATTORNEY OF RECORD David C. Andersen
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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**Authority For Civil Cover Sheet**

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

David C. Andersen
CA Bar No. 194095
The Miller Firm, LLC
108 Railroad Avenue
Orange, VA 22960

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

RICHARD MORA,

Plaintiff,

v.

**ASTRAZENECA
PHARMACEUTICALS, LP,
ASTRAZENECA LP.**

Defendants.

Case No. **2793**

CIVIL COMPLAINT

JURY TRIAL DEMANDED

COMES NOW the Plaintiff, by and through his undersigned attorney, and for his Complaint against AstraZeneca Pharmaceuticals LP and AstraZeneca, LP, (hereinafter "AstraZeneca" or "Defendants") and alleges as follows:

1. This action is brought by Plaintiff seeking damages for personal injuries and economic damages suffered as a result of a defective and dangerous pharmaceutical product, Seroquel, which was manufactured, marketed, distributed and/or sold by AstraZeneca to the general public.

JURISDICTION AND VENUE

2. The Court has jurisdiction over this lawsuit under 28 U.S.C. § 1332 as the amount

1 in controversy exceeds \$75,000, excluding interest and costs and there is diversity of the parties.
2 Venue is proper in this district based upon Defendants' commercial activities and Plaintiff's place
3 of residence.

4 3. Defendants placed the dangerous and defective pharmaceutical atypical
5 antipsychotic drug Seroquel into the stream of interstate and worldwide commerce, including the
6 State of California.

7 4. As a direct and proximate result of Defendants placing Seroquel into the stream of
8 commerce, Plaintiff has suffered and continues to suffer injuries including, but not limited to
9 physical, mental and economic loss, pain and suffering, and she will continue to experience such
10 injuries indefinitely.

11 5. Upon information and belief, at all relevant times, Defendants were present and
12 transacted, solicited and conducted business in the State of California and derived substantial
13 revenue from such business.

14 6. At all relevant times, Defendants expected or should have expected that their acts
15 would have consequences within the United States and the State of California.

16 7. This action includes claims for injuries to Plaintiff caused by his ingestion of
17 Seroquel and therefore should be, and plaintiff consents to, transfer to **Multidistrict Litigation**
18 **No. 1769 In Re: Seroquel Products Liability Litigation**, United States District Court, Middle
19 District of Florida, Orlando Division, the Honorable Anne C. Conway.

20 **PARTIES**

21 8. Plaintiff, Richard Mora, is a resident of Rohnert Park, California. Richard Mora
22 was prescribed, purchased and ingested Seroquel. After using Seroquel, Plaintiff was diagnosed
23 with Diabetes Mellitus.

24 9. AstraZeneca Pharmaceuticals LP, is a Delaware limited partnership doing business
25
26
27
28

1 in the State of Delaware, and the United States. AstraZeneca Pharmaceuticals LP, is the United
2 States Subsidiary of AstraZeneca PLC, and was created as a result of the union of Zeneca
3 Pharmaceuticals and Astra Pharmaceuticals LP in the United States after the 1999 merger.
4 AstraZeneca Pharmaceuticals LP's principal place of business is in Delaware, 1800 Concord
5 Pike, P.O. Box 15347, Wilmington, Delaware 19850. Upon information and belief AstraZeneca
6 Pharmaceuticals LP's general and limited partners are: AstraZeneca AB, a Swedish corporation
7 with its principal place of business in Sweden; Zeneca Inc., a Delaware corporation with its
8 principal place of business in Delaware; Astra USA Inc., a New York corporation with it's
9 principal place of business in Delaware; and Astra US Holdings Corporation, A Delaware
10 corporation with it's principal place of business in Delaware. Therefore, AstraZeneca
11 Pharmaceuticals LP is a citizen of Delaware, New York and Sweden.
12

13
14 10. Defendant, AstraZeneca LP, is a Delaware limited partnership doing business in
15 the State of Delaware and the United States. AstraZeneca LP's principal place of business is in
16 Delaware. Upon information and belief AstraZeneca LP's general partner is AstraZeneca
17 Pharmaceuticals LP, which as stated above is a citizen of Delaware, New York, and Sweden.
18 AstraZeneca LP's sole limited partner, KBI Sub Inc., is incorporated in the State of Delaware and
19 its principal place of business is in New Jersey. Therefore, AstraZeneca LP is a citizen of
20 Delaware, New York, New Jersey and Sweden.
21

22 11. AstraZeneca Pharmaceuticals LP, and AstraZeneca LP shall be collectively
23 referred to as "AstraZeneca" or "Defendants". At all times relevant herein, the Defendants' were
24 in the business of designing, testing, monitoring, manufacturing, labeling, advertising, marketing,
25 promoting, selling and distributing pharmaceuticals, including Seroquel, for the use by the
26 mainstream public, including Plaintiff.
27
28

FACTUAL BACKGROUND

12. This is an action against the AstraZeneca Defendants on behalf of the Plaintiff who was prescribed the prescription drug Seroquel, which is an “anti-psychotic” medication belonging to a class of drugs referred to as “atypical anti-psychotics”.

13. Plaintiff ingested the prescribed dosage of said drug in accordance with the prescription written for the Plaintiff.

14. Seroquel causes serious and sometimes fatal injuries including but not limited to, ketoacidosis, pancreatitis, and diabetes mellitus, and other serious health problems associated with the onset of diabetes including heart disease, blindness, coma, seizures and death.

15. At all times relevant herein, the AstraZeneca Defendants, either directly or through their agents, servants, and employees, designed, manufactured, marketed, advertised, distributed, and sold Seroquel for the treatment of schizophrenia, bipolar disorder, and other "off-label" uses.

16. Those persons who were prescribed and ingested Seroquel, including Plaintiff, have suffered severe and permanent personal injuries, including diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, diabetic coma, and death, as well as other severe and permanent injuries.

History of Seroquel

17. In September 1997, the Food and Drug Administration (“FDA”) approved the newest “atypical anti-psychotic,” Seroquel, for use in the United States. At that time, Seroquel was approved for use in dosages of 25 mg, 100 mg and 200mg tablets.

18. Seroquel is now available in 25 mg, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg dosages.

19. The prescription drug Seroquel is an “anti-psychotic” medication, belonging to a class of drugs referred to as “atypical anti-psychotics”. Other atypical anti-psychotics include

1 Zyprexa (Eli Lilly), Risperdal (Johnson & Johnson) and Abilify (Bristol-Myers Squibb), which
2 have been in use in the United States since the early to mid 1990's.

3 20. Seroquel is a medication commonly prescribed to patients to aid in the treatment of
4 mental disorders including schizophrenia. The pharmacologic action of Seroquel is thought to be
5 dependent on its ability to block or moderate the level of dopamine, a chemical found in the brain
6 that in excessive amounts is believed to cause abnormal thinking and hallucinations. It appears to
7 work primarily by blocking neurotransmitter sites of serotonin and dopamine, as well as
8 histamine receptors.
9

10 21. Seroquel was widely advertised, marketed and represented by the AstraZeneca
11 Defendants, in its label, package insert, *Physicians Desk Reference* entry and otherwise, as a safe
12 and effective atypical anti-psychotic.
13

14 22. Seroquel was marketed heavily by the AstraZeneca Defendants as a safe and
15 effective treatment for schizophrenia and the AstraZeneca Defendants' promised fewer side
16 effects than other similar treatments including the other atypical anti-psychotics on the market.

17 23. The AstraZeneca Defendants, through their marketing departments, sales
18 managers, and field sales force and other agents, servants and employees promoted the drug for
19 uses beyond its approved indications, offering incentives to doctors to increase prescriptions.
20 Through these marketing efforts, the AstraZeneca Defendants were able to capture a larger
21 market share in the anti-psychotic market.
22

23 24. These marketing efforts were designed and implemented to create the impression
24 in physicians', patients' and plaintiff's minds that Seroquel was safe and effective and that it
25 carried less risk of side effects and adverse reactions than other available treatments.

26 25. The marketing and promotion efforts of the AstraZeneca Defendants, their agents,
27 servants and/or employees served to overstate the benefits of Seroquel and minimize and
28

1 downplay the risks associated with the drug.

2 26. On May 6, 1999, the AstraZeneca Defendants were told by the FDA that materials
3 they continued to distribute, despite a warning letter dated November 24, 1998, were "determined
4 to be false, lacking in fair balance, or otherwise misleading, and in violation of the Federal Food,
5 Drug and Cosmetic Act and the regulations promulgated thereunder."

6 27. The FDA had specific objections to numerous promotional materials that they
7 directed be "[I]mmediately discontinued...". These objections involved the AstraZeneca
8 Defendants use of promotional materials and included the following:
9

- 10 a. Materials that state or imply that Seroquel is effective in a broader range of
11 mental conditions, including bipolar disorder and schizoaffective disorder,
12 are misleading (e.g., brochures #SQ1035, #SQ1112). Seroquel is indicated
13 for the manifestations of psychotic disorders as determined by clinical
14 trials in schizophrenic inpatients. Application to broader or additional
15 mental disorders would require substantiation from adequate and well-
16 controlled studies designed to examine the specific mental conditions.
- 17 b. The mechanism of action of Seroquel, as well as other antipsychotic drugs,
18 is unknown. Therefore, materials that discuss how Seroquel "works"
19 without stressing the theoretical nature of this information, are misleading
20 (e.g., brochures #SQ1059, #PR1048).
- 21 c. Materials in which the prominence and readability of the risk information
22 fails to be reasonably comparable to the information regarding the
23 effectiveness of Seroquel lack fair balance (e.g., journal ad #SQ1089,
24 brochure #SQ1139). In addition, materials that fail to disclose the
25 important warnings and precautions (i.e., neuroleptic malignant syndrome,
26 tardive dyskinesia, orthostatic hypotension, risk of cataract development,
27 and seizures) are lacking fair balance because these are considered to be
28 priority safety consideration (e.g., journal #SQ1088).

21 28. The AstraZeneca Defendants made affirmative assertions of material fact
22 including but not limited to Seroquel was safe if used as directed, no specific laboratory tests
23 were recommended and Seroquel was safer than other alternative medications.

24 29. The AstraZeneca Defendants knew these assertions to be false or recklessly failed
25 to ascertain their truth or falsity.

26 30. The AstraZeneca Defendants also fraudulently concealed important safety
27 information from physicians, the FDA, the public and Plaintiff, including but not limited to the
28

1 AstraZeneca Defendants' awareness of numerous reports of diabetes associated with the use of
2 Seroquel, beyond the background rate, and beyond the rate for other anti-psychotic agents. The
3 AstraZeneca Defendants as manufacturers of ethical drugs had a duty to disclose said
4 information.

5
6 31. The AstraZeneca Defendants were aware that the drug caused diabetes mellitus,
7 pancreatitis and ketoacidosis, but the AstraZeneca Defendants concealed such information and
8 made misrepresentations that the drug was safe.

9 32. The anti-psychotic drug market is one of the largest drug markets worldwide.

10 33. The AstraZeneca Defendants viewed Seroquel as a blockbuster product with
11 significant projected growth potential. In 2002 alone, Seroquel reached over \$1.1 Billion in sales.

12 34. Upon information and belief, Seroquel is one of the AstraZeneca Defendants' top-
13 selling drugs.

14
15 35. Since the AstraZeneca Defendants introduced Seroquel in 1997, over 24.6 million
16 prescriptions have been made and it has been prescribed to more than 13 million people
17 worldwide.

18 36. In 2003, approximately seven million prescriptions for Seroquel were dispensed,
19 resulting in more than \$2 Billion in sales.

20 37. In 2005, Seroquel reached approximately \$2.7 Billion in annual sales and
21 controlled approximately 31% of the market share for atypical anti-psychotics.

22 38. Worldwide sales for Seroquel in the first quarter of 2006 compared with sales a
23 year ago in the same period were \$807 million, up 27 percent.

24
25 **Adverse Effects Related To Seroquel Use**

26 39. In an extensive independent study of over 8,000 New York mental health patients,
27 published in September of 2004, it was found that the risk of diabetes was over 300% higher in
28

1 patients who took Seroquel.

2 40. The use of Seroquel is now known by the public, the FDA and physicians to cause
3 serious and sometimes fatal injuries including, but not limited to, ketoacidosis, pancreatitis, and
4 diabetic mellitus, and other serious health problems associated with diabetes including heart
5 disease, blindness, coma, seizures and death.

6
7 41. In August 2003, the AstraZeneca Defendants became further aware of the link
8 between Seroquel and diabetes. These new reports, described an increased incidence of diabetes
9 in patients receiving Seroquel, than in patients receiving older anti-psychotics, or even other
10 atypicals, including Zyprexa, Clozaril and Risperdal.

11 42. The reported risk associated with Seroquel and the onset of diabetes is nearly 3.34
12 times higher than older drugs used to treat schizophrenia, such as Haldol. According to these
13 reports, compared to other drugs in its class, Zyprexa, (Eli Lilly & Co.) - 1.27 times more likely,
14 and Risperdal (Johnson & Johnson) - 1.49 times more likely, Seroquel has a much greater
15 increased association with the onset of diabetes mellitus than any other anti-psychotic on the
16 market.

17
18 43. Consumers, including Plaintiff, who have used Seroquel, have available several
19 alternative atypical anti-psychotic medications.

20
21 44. In fact, in December 2000, the AstraZeneca Defendants knew that there was no
22 clear evidence that Seroquel was more effective or better tolerated than conventional anti-
23 psychotics including Haldol and Thorazine.

24 45. It should be noted that there is a significant difference among the costs of Haldol
25 and Seroquel per month: \$35 versus \$414, respectively.

26 **Seroquel Causes Diabetes and Other Serious Injuries**

27 46. Shortly after the AstraZeneca Defendants began selling Seroquel, the AstraZeneca
28

1 Defendants began to receive reports of consumers who were using Seroquel suffering from
2 hyperglycemia, acute weight gain, exacerbation of diabetes mellitus (hereinafter Adiabetes@),
3 development of diabetes, pancreatitis, and other severe diseases and conditions. The AstraZeneca
4 Defendants knew, or should have been aware of these reports.

5
6 47. By July 2001, the AstraZeneca Defendants had received at least 46 reports of
7 patients taking Seroquel and developing hyperglycemia or diabetes mellitus, of which there were
8 21 cases of ketoacidosis or acidosis and 11 deaths. By December 31, 2003, the AstraZeneca
9 Defendants had received reports of at least 23 additional cases, bringing the total to 69. Most of
10 these patients developed the above conditions within six months of their use of Seroquel.

11
12 48. The AstraZeneca Defendants were or should have been aware of studies and
13 articles in 1998 and 1999 confirming a link between drugs like Seroquel and new onset diabetes
14 and permanent hyperglycemia related adverse events. *Wirshing, DA, Novel Antipsychotics and*
15 *New Onset Diabetes. Biol. Psychiatry, 1998;15, 44:778-83; Allison, DB, Antipsychotic-Induced*
16 *Weight Gain: A Comprehensive Research Synthesis. Am. J. Psychiatry, 1999;156:1686-96.*

17
18 49. Studies conducted in the United States and Europe have established that numerous
19 patients treated with Seroquel experienced a significantly higher incidence of severe and
20 permanent diseases and conditions, including dangerous rises in blood glucose levels.

21 **Defendants' Failure to Warn of the Dangers of Seroquel**

22
23 50. At the time of the prescription of Seroquel to the Plaintiff, the AstraZeneca
24 Defendants had not adequately warned Plaintiff or his/her physicians, and/or did not adequately
25 and effectively communicate all warnings about the risk of diabetes, hyperglycemia, diabetic
26 ketoacidosis, or other serious injuries caused by Seroquel.

27
28 51. The product warnings for Seroquel in effect during the relevant time period were
vague, incomplete or otherwise inadequate, both substantively and graphically, to alert

1 prescribing physicians as well as consumer patients of the actual risks presented by the use of this
2 drug.

3 52. In fact, the product information section for Seroquel in the *Physicians Desk*
4 *Reference* for the years 1999, 2000, 2001, 2002, 2003 and 2004, contains no statement in the
5 WARNINGS section to alert anyone of the risks of diabetes, ketoacidosis or pancreatitis
6 associated with the use of Seroquel.
7

8 53. However, in Japan, the AstraZeneca Defendants warned of the risks of diabetes
9 since 2002.

10 54. The Japanese "label" for Seroquel provides, and has provided since 2002, a
11 detailed warning regarding the risks of diabetes associated with Seroquel, and specifically
12 informs physicians regarding the necessity of monitoring patients on Seroquel. At the time
13 Plaintiff ingested Seroquel, the AstraZeneca Defendants had not adopted this label for the
14 distribution of Seroquel in the United States.
15

16 55. The label the AstraZeneca Defendants issued in Japan, but not in the United States,
17 warns specifically of the diabetes risk, prominently in the beginning of the package label stating:

- 18 a. Quetiapine is contraindicated for use in patients with diabetes or a history
19 of diabetes;
- 20 b. Quetiapine should be used with caution in patients with risk factors for
21 diabetes, including hyperglycemia, obesity or a family history of diabetes;
- 22 c. Patients receiving quetiapine should be carefully monitored for symptoms
23 of hyperglycemia and the drug should be discontinued if such symptoms
24 occur. The symptoms of severe hyperglycemia include weakness,
25 excessive eating, excessive thirst, and excessive urination; and,
- 26 d. Physicians should educate patients and their family members about the risk
27 of serious hyperglycemia associated with quetiapine and how to identify
28 the symptoms of hyperglycemia.

29 56. On September 11, 2003, the FDA informed the AstraZeneca Defendants that they
30 must make labeling changes to Seroquel, due to an increasing prevalence of diabetes-related
31 illnesses associated with this drug. The following information appeared in the WARNINGS

1 section for Seroquel in the 2005 *Physicians Desk Reference*:

2 Hyperglycemia, in some cases extreme and associated with ketoacidosis or
3 hyperosmolar coma or death, has been reported in patients treated with
4 atypical antipsychotics, including Seroquel. Assessment of the relationship
5 between atypical antipsychotic use and glucose abnormalities is
6 complicated by the possibility of an increased background risk of diabetes
7 mellitus in patients with schizophrenia and the increasing incidence of
8 diabetes mellitus in the general population. Given these confounders, the
9 relationship between atypical antipsychotic use and hyperglycemia-related
10 adverse events is not completely understood. However, epidemiologic
11 studies suggest an increased risk of treatment emergent hyperglycemia-
12 related adverse events in patients treated with atypical antipsychotics.
13 Precise risk estimates for hyperglycemia-related adverse events in patients
14 treated with atypical antipsychotics are not available.

15 Patients with an established diagnosis of diabetes mellitus who are started
16 on atypical antipsychotics should be monitored regularly for worsening of
17 glucose control. Patients with risk factors for diabetes mellitus (e.g.,
18 obesity, family history of diabetes) who are starting treatment with atypical
19 antipsychotics should undergo fasting blood glucose testing at the
20 beginning of treatment and periodically during treatment. Any patient
21 treated with atypical antipsychotics should be monitored for symptoms of
22 hyperglycemia including polydipsia, polyuria, polyphagia, and weakness.
23 Patients who develop symptoms of hyperglycemia during treatment with
24 atypical antipsychotics should undergo fasting blood glucose testing. In
25 some cases, hyperglycemia has resolved when the atypical antipsychotic
26 was discontinued; however, some patients required continuation of anti-
27 diabetic treatment despite discontinuation of the suspect drug.

28 57. Recently, researchers at the National Institute of Mental Health published a
report on atypical anti-psychotics, including Seroquel, which found that the majority of
patients in each group discontinued their assigned treatment owing to inefficacy or
intolerable side effects or for other reasons and that the atypicals, including Seroquel,
were no more effective than the older, cheaper, and still available conventional
antipsychotic perphenazine. This report echoes the conclusions reported in the *British
Medical Journal* in 2000.

 58. The AstraZeneca Defendants misrepresented and failed to appropriately warn
consumers, including Plaintiff, and the medical and psychiatric communities of the dangerous
risk of developing diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma,
as well as other severe and permanent health consequences caused by Seroquel, and consequently
placed their profits above the safety of its customers.

59. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require constant and continuous medical care and treatment.

Plaintiff's Use of Seroquel

60. Plaintiff was prescribed and began taking Seroquel as prescribed by his/her prescriber.

61. Plaintiff used Seroquel as prescribed and in a foreseeable manner.

62. As a direct and proximate result of using Seroquel, Plaintiff was seriously injured and developed the permanent, life threatening condition of diabetes.

63. Plaintiff, as a direct and proximate result of ingesting Seroquel, has suffered severe pain and has sustained permanent injuries and emotional distress.

64. Had Plaintiff known of the full extent of the risks and dangers associated with Seroquel, Plaintiff would not have taken Seroquel.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

65. The running of any statute of limitation has been tolled by reason of the AstraZeneca Defendants' fraudulent conduct. The AstraZeneca Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true risks associated with taking Seroquel.

66. As a result of the AstraZeneca Defendants actions, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the AstraZeneca Defendants' acts and omissions.

67. Furthermore, the AstraZeneca Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the truth, quality and nature of Seroquel. The AstraZeneca Defendants were under a duty to disclose the true character, quality and nature

1 of Seroquel because this was a non-public information over which the AstraZeneca Defendants
2 had and continue to have exclusive control, and because the Defendants knew that this
3 information was not available to the Plaintiff, medical providers and/or to health facilities. In
4 addition, the AstraZeneca Defendants are estopped from relying on any statute of limitation
5 because of their intentional concealment of these facts.
6

7 68. The Plaintiff had no knowledge that the AstraZeneca Defendants were engaged in
8 the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing
9 by the AstraZeneca Defendants, Plaintiff could not have reasonably discovered the wrongdoing at
10 any time prior. Also, the economics of this fraud should be considered. The AstraZeneca
11 Defendants had the ability to and did spend enormous amounts of money in furtherance of their
12 purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably
13 known risks. Plaintiff and his/her medical professionals could not have afforded and could not
14 have possibly conducted studies to determine the nature, extent and identity of related health
15 risks, and were forced to rely on the AstraZeneca Defendants' representations.
16

17
18 **COUNT I**
NEGLIGENCE

19 69. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
20 fully set forth herein and further alleges as follows:
21

22 70. The AstraZeneca Defendants were in the business of testing, designing,
23 manufacturing, packaging, promoting, distributing, performing quality assurance evaluations
24 and/or selling Seroquel.

25 71. The AstraZeneca Defendants owed a duty of reasonable care to Plaintiff to license,
26 test, design, manufacture, package, properly and adequately warn, promote, distribute, perform
27 quality assurance evaluations, and/or sell Seroquel in a safe condition.
28

1 72. The AstraZeneca Defendants had a duty not to introduce a pharmaceutical drug,
2 such as Seroquel, into the stream of commerce that caused users of said drug, including Plaintiff
3 to suffer from unreasonable, dangerous and adverse side effects.

4 73. The AstraZeneca Defendants breached their duty in that they and/or their agents
5 servants or employees failed to exercise reasonable care and were negligent and/or were reckless
6 in the licensing, testing, quality assurance, design, manufacture, packaging, warning, advertising,
7 promotion, distribution and sale of the product.

8 74. The AstraZeneca Defendants' conduct was wanton, reckless and malicious so as to
9 permit the recovery of punitive damages.

10 75. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and
11 economic loss.

12 76. As a direct and proximate result of one or more of these wrongful acts or
13 omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered
14 profound injuries which are permanent and continuing in nature; required and will require
15 medical treatment and hospitalization; have become and will become liable for medical and
16 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
17 activities and duties and have and will continue to experience mental and physical pain and
18 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
19 future.

20 **WHEREFORE**, Plaintiff demands judgment against each of the AstraZeneca Defendants
21 individually, jointly and/or severally for all such compensatory, statutory and punitive damages
22 available under applicable law, together with interest, costs of suit, attorneys' fees and all such
23 other relief as the Court deems proper.

24 **COUNT II**
25 **COMMON LAW FRAUD**

1 77. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
2 fully set forth herein and further alleges as follows:

3 78. As set forth under the facts herein, and pending discovery, the AstraZeneca
4 Defendants' representatives through national advertising, promotional campaigns, standardized
5 package inserts, related materials, purchased or subsidized so-called expert opinions both orally
6 and in print and in correspondence to healthcare professionals, and in submissions and reports to
7 the FDA, and product information regarding the characteristics of and the quality of Seroquel,
8 were false, misleading, materially incorrect in fact, and were made knowingly, intentionally,
9 and/or willfully to deceive without regard to the safety and use of the product and were acted on
10 in reasonable reliance by Plaintiff's prescribing physicians and medical professionals and
11 Plaintiff, to Plaintiff's substantial detriment and injury.

12
13 79. The AstraZeneca Defendants distributed false and misleading materials to
14 physicians, Plaintiff's prescribers and Plaintiff that the FDA "determined to be false, lacking in
15 fair balance, or otherwise misleading, and in violation of the Federal Food, Drug and Cosmetic
16 Act and the regulations promulgated thereunder."

17
18 80. The FDA directed that the AstraZeneca Defendants discontinued the use of various
19 promotional materials that were distributed to physicians, Plaintiff's prescribers and Plaintiff and
20 stated as follows:

- 21
22 a. Materials that state or imply that Seroquel is effective in a broader range of mental
23 conditions, including bipolar disorder and schizoaffective disorder, are misleading
24 (e.g., brochures #SQ1035, #SQ1112). Seroquel is indicated for the manifestations
25 of psychotic disorders as determined by clinical trials in schizophrenic inpatients.
26 Application to broader or additional mental disorders would require substantiation
27 from adequate and well-controlled studies designed to examine the specific mental
28 conditions.
- b. The mechanism of action of Seroquel, as well as other antipsychotic drugs, is
unknown. Therefore, materials that discuss how Seroquel "works" without
stressing the theoretical nature of this information, are misleading (e.g., brochures
#SQ1059, #PR1048).
- c. Materials in which the prominence and readability of the risk information fails to
be reasonably comparable to the information regarding the effectiveness of

1 Seroquel lack fair balance (e.g., journal ad #SQ1089, brochure #SQ1139). In
2 addition, materials that fail to disclose the important warnings and precautions
3 (i.e., neuroleptic malignant syndrome, tardive dyskinesia, orthostatic hypotension,
risk of cataract development, and seizures) are lacking fair balance because these
are considered to be priority safety consideration (e.g., journal #SQ1088).

4 81. Material information concerning the development of a serious injury related to the
5 use of Seroquel was fraudulently concealed by the AstraZeneca Defendants from Plaintiff's
6 treating physicians and Plaintiff. The FDA had received reports of 11 Seroquel related deaths and
7 numerous diabetes related injuries. The AstraZeneca Defendants knew or reasonably should have
8 known of this information and this information was not disclosed to Plaintiff's physicians or to
9 Plaintiff.
10

11 82. As part of the warning label in Japan, the AstraZeneca Defendants were required
12 to disclosed that individuals with diabetes or a family history of diabetes should not take
13 Seroquel. This important and material information was not communicated to Plaintiff's
14 physicians or to Plaintiff in the United States.
15

16 83. The AstraZeneca Defendants intended that the Plaintiff's physicians and patients,
17 including Plaintiff would rely upon such misrepresentations.

18 84. The AstraZeneca Defendants' representations as set forth above regarding the
19 quality and characteristics of Seroquel were willful and/or reckless misrepresentations of material
20 fact made with the intent to induce Plaintiff and Plaintiff did, without knowledge of their falsity,
21 directly or indirectly, justifiably act upon those willful misrepresentations to Plaintiff's injury.
22

23 85. Plaintiff relied to their detriment on these material misrepresentations and suffered
24 serious injuries including but not limited to diabetes mellitus, ketoacidosis and pancreatitis.

25 86. As a result of the foregoing, Plaintiff was caused bodily injury, pain, suffering and
26 economic loss.

27 87. As a direct and proximate result of one or more of these wrongful acts or
28 omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered

1 profound injuries which are permanent and continuing in nature; required and will require
2 medical treatment and hospitalization; have become and will become liable for medical and
3 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
4 activities and duties and have and will continue to experience mental and physical pain and
5 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
6 future.
7

8 **WHEREFORE**, Plaintiff demands judgment against each of the AstraZeneca Defendants
9 individually, jointly and/or severally for all such compensatory, statutory and punitive damages
10 available under applicable law, together with interest, costs of suit, attorneys' fees and all such
11 other relief as the Court deems proper.
12

13 **COUNT III**
14 **FRAUDULENT CONCEALMENT**

15 88. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
16 fully set forth herein and further alleges as follows:

17 89. As set forth under the facts herein, and pending discovery, the AstraZeneca
18 Defendants fraudulently concealed from the Plaintiff's physicians and Plaintiff that Seroquel was
19 dangerous and not as effective for its purpose as represented, and imposed greater risks than
20 disclosed.
21

22 90. The AstraZeneca Defendants as the manufacturer of ethical drugs were under a
23 duty to timely disclose adequate warnings and information to the medical profession, Plaintiff's
24 prescribers and Plaintiff under laws requiring them not to engage in false and deceptive trade
25 practices, and because the AstraZeneca Defendants were experts in the field, they are under a
26 continuous duty to keep abreast of scientific developments touching on Seroquel and to know the
27 true state of the facts about the dangerous and defective nature of Seroquel.
28

91. The AstraZeneca Defendants had actual knowledge gained from research and

1 adverse event reports and constructive knowledge from scientific literature and other means of
2 communication to know of the true risks of Plaintiff's use of Seroquel. This medical information
3 was fraudulently concealed from Plaintiff's physicians and Plaintiff.

4 92. Material information concerning the development of a serious injury related to the
5 use of Seroquel was fraudulently concealed from Plaintiff's treating physicians and Plaintiff. The
6 FDA had received reports of 11 Seroquel related deaths and numerous diabetes related injuries.
7 The AstraZeneca Defendants knew or reasonably should have known of this information and this
8 information was not disclosed to Plaintiff's physicians or to Plaintiff.

9 93. Significantly, the AstraZeneca Defendants were required to disclose in Japan
10 specific information that individuals with diabetes or a family history of diabetes should not take
11 Seroquel. This important and significant information was not communicated to Plaintiff's
12 physicians or to Plaintiff in the United States.

13 94. The AstraZeneca Defendants also concealed information that in Japan they had
14 warned, that if a patient developed symptoms of hyperglycemia, then patients should be carefully
15 monitored and Seroquel should be discontinued. This material information was not disclosed and
16 was fraudulently concealed from Plaintiff's physicians and Plaintiff in the United States.

17 95. These intentional representations suppressed and/or concealed material facts,
18 including but not limited to:

- 19
- 20 a. suppressing and/or mischaracterizing the known risks to health and
21 effectiveness;
 - 22 b. failing to timely and fully disclose the results of tests and studies on the
23 risks to health and effectiveness;
 - 24 c. failing to disseminate adequate warnings which would disclose the nature
25 and extent of the side effects of the product, the risks to health and
26
27
28

1 effectiveness;

2 d. failing to disclose that adequate and/or standard and/or generally accepted
3 standards for pre-clinical testing had not been done;

4 e. failing to disclose that adequate and/or standard and/or generally accepted
5 standards for post-marketing testing had not been done;

6 f. failing to disclose that alternative products and methods available posed
7 less risks than Seroquel and were at least effective;

8 g. failing to conduct adequate tests and studies on the product prior to
9 marketing and making representations as set forth in this complaint;

10 h. failing to reveal the full nature and extent of the known risks and hazards
11 associated with Seroquel; and

12 i. as otherwise described in this complaint to be discovered during this
13 litigation and to be proven at trial.

14
15
16 96. Plaintiff had no knowledge of the dangerous risks associated with the use of
17 Seroquel and relied on the AstraZeneca Defendants fraudulent representations and suffered injury
18 as a result thereof.

19 97. Plaintiff could not have taken any action to reasonably discover that the
20 AstraZeneca Defendants representations were false and fraudulent.

21 98. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and
22 economic loss.

23
24 99. As a direct and proximate result of one or more of these wrongful acts or
25 omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered
26 profound injuries which are permanent and continuing in nature; required and will require
27 medical treatment and hospitalization; have become and will become liable for medical and
28

1 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
2 activities and duties and have and will continue to experience mental and physical pain and
3 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
4 future.

5
6 **WHEREFORE**, Plaintiff demands judgment against each of the AstraZeneca Defendants
7 individually, jointly and/or severally for all such compensatory, statutory and punitive damages
8 available under applicable law, together with interest, costs of suit, attorneys' fees and all such
9 other relief as the Court deems proper.

10
11 **COUNT IV**
FAILURE TO ADEQUATELY WARN

12 100. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
13 fully set forth herein and further alleges as follows:

14
15 101. The AstraZeneca Defendants, as a manufacturer of pharmaceuticals, had a duty to
16 warn of adverse drug reactions, which they know or have reason to know, are inherent in the use
17 of its pharmaceutical products.

18 102. The AstraZeneca Defendants failed to adequately warn Plaintiff, Plaintiff's
19 physicians and the general public of the risks of Seroquel being used by Plaintiff.

20 103. The AstraZeneca Defendants failed to adequately warn of dangers inherent with
21 the use of Seroquel and the AstraZeneca Defendants misrepresentations and inadequate
22 disclosures to the Plaintiff's physicians, Plaintiff, and the general public, made the product
23 unreasonably dangerous for normal use.

24
25 104. The AstraZeneca Defendants are strictly liable in tort to the Plaintiff upon the
26 grounds that:

27 a. Seroquel was unsafe, defective and unreasonably dangerous for its
28

1 intended and/or foreseeable uses, by reason of inadequately warning and/or
2 inadequately communicating warnings.

3 b. In distributing, promoting and selling Seroquel not accompanied by
4 adequate warnings of the dangers that were known or should have been
5 known; by failing to provide adequate warnings regarding all known or
6 reasonably knowable potential side effects associated with the use of
7 Seroquel, and the comparative nature, extent, severity, incidence and
8 duration of such adverse effects; failing to provide adequate warnings
9 regarding the signs, symptoms, incidence, scope or severity of the side
10 effects, and/or identify appropriate testing, monitoring and/or remedial
11 action; failing to provide adequate warnings in a timely manner and
12 information necessary for their purposes, thus placing the Plaintiff and
13 consuming public at risk;

14 c. The AstraZeneca Defendants were aware that Seroquel would be used
15 without inspection and study for the defects inherent in Seroquel as
16 alleged, and that given the resources of the Plaintiff and his/her physicians,
17 any reasonably anticipated inspection would have failed to detect the
18 defects;

19 d. The AstraZeneca Defendants expected and knew that Seroquel would reach
20 the consuming public and Plaintiff. Seroquel was, in fact, received by
21 Plaintiff without change in the condition in which the drug and its labeling
22 was first manufactured and sold.

23 e. Plaintiff was a foreseeable users of the product in its intended manner and
24 suffered serious harm because of said use.
25
26
27
28

105. The Seroquel manufactured and/or supplied by the AstraZeneca Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the AstraZeneca Defendants knew or should have known of the risks of injury from Seroquel use, they failed to provide adequate warnings to consumers of the product, including Plaintiff, and continued to aggressively promote Seroquel.

106. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and economic loss.

107. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff demands judgment against each of the AstraZeneca Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
STRICT LIABILITY-DEFECTIVE DESIGN

108. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

109. The Seroquel manufactured and/or supplied by the AstraZeneca Defendants was placed into the stream of commerce in a defective and unreasonably unsafe condition in that the

1 foreseeable risks of its use exceeded the benefits associated with the design or formulation.

2 110. The AstraZeneca Defendants knew or should have known at the time of
3 manufacture that Seroquel was defective in design or formulation and that Sequel created a risk of
4 harm to consumers such as Plaintiff when used in the way it was intended to be used and in a
5 manner which was reasonably foreseeable by the AstraZeneca Defendants.
6

7 111. The Seroquel manufactured and/or supplied by the AstraZeneca Defendants was
8 placed into the stream of commerce when they knew or should have known of the defective
9 design or formulation and a reasonable person would have concluded that the utility of Seroquel
10 did not outweigh the risk inherent in marketing Seroquel designed in that manner.
11

12 112. As set forth in this complaint and otherwise, the AstraZeneca Defendants knew of
13 Seroquel's defective nature at the time of its manufacture, but continued to design, manufacture,
14 market, promote, represent to the consuming public, prescribers, and Plaintiff that Seroquel was
15 safe for the sole purpose of maximizing sales and profits at the expense of the public health and
16 safety in conscious disregard of foreseeable harm caused by Seroquel.

17 113. By reason of the foregoing, Plaintiff was caused bodily injury, pain, suffering and
18 economic loss.
19

20 114. As a direct and proximate result of one or more of these wrongful acts or
21 omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered
22 profound injuries which are permanent and continuing in nature; required and will require
23 medical treatment and hospitalization; have become and will become liable for medical and
24 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
25 activities and duties and have and will continue to experience mental and physical pain and
26 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
27 future.
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120. As a direct and proximate result of one or more of these wrongful acts or omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered

1 profound injuries which are permanent and continuing in nature; required and will require
2 medical treatment and hospitalization; have become and will become liable for medical and
3 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
4 activities and duties and have and will continue to experience mental and physical pain and
5 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
6 future.
7

8 **WHEREFORE**, Plaintiff demands judgment against each of the AstraZeneca Defendants
9 individually, jointly and/or severally for all such compensatory, statutory and punitive damages
10 available under applicable law, together with interest, costs of suit, attorneys' fees and all such
11 other relief as the Court deems proper.
12

13 **COUNT VII**
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

14 121. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
15 fully set forth herein and further alleges as follows:

16 122. The AstraZeneca Defendants impliedly warranted that it would sell and deliver
17 Seroquel in a condition that was fit for the particular purposes for which it was intended.
18

19 123. The AstraZeneca Defendants knew that Plaintiff intended to use the Seroquel for
20 the particular purpose of medication and that as such, that the medication needed to be safe for
21 use by Plaintiff.

22 124. Plaintiff relied upon the AstraZeneca Defendants' skill and/or judgment in their
23 ability to furnish suitable Seroquel that was safe for its intended use.

24 125. The Seroquel was not safe for its intended use in that it was defective and caused
25 serious side effects and the AstraZeneca Defendants therefore breached its implied warranty of
26 fitness for a particular purpose.
27

28 126. As a direct and proximate result of the foregoing, Plaintiff was caused bodily

1 injury, pain and suffering and economic loss.

2 127. As a direct and proximate result of one or more of these wrongful acts or
3 omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered
4 profound injuries which are permanent and continuing in nature; required and will require
5 medical treatment and hospitalization; have become and will become liable for medical and
6 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
7 activities and duties and have and will continue to experience mental and physical pain and
8 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
9 future.
10

11 **WHEREFORE**, Plaintiff demands judgment against each of the AstraZeneca Defendants
12 individually, jointly and/or severally for all such compensatory, statutory and punitive damages
13 available under applicable law, together with interest, costs of suit, attorneys' fees and all such
14 other relief as the Court deems proper.
15

16 **COUNT VIII**
17 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

18 128. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
19 fully set forth herein and further alleges as follows:

20 129. At all times material hereto, the AstraZeneca Defendants marketed, sold and
21 distributed Seroquel and knew and promoted the use for which the aforesaid drug was being used
22 by Plaintiff and impliedly warranted to Plaintiff that Seroquel was of merchantable quality and fit
23 for the ordinary purpose for which it was intended.
24

25 130. Plaintiff reasonably relied on the skill, expertise and judgment of the AstraZeneca
26 Defendants and its representations as to the fact that Seroquel was of merchantable quality.

27 131. The Seroquel manufactured and supplied by the AstraZeneca Defendants was not
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1 of merchantable quality, as warranted by the AstraZeneca Defendants in that the drug had
2 dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which
3 it was intended.

4 132. As a direct and proximate result of the foregoing, Plaintiff was caused bodily
5 injury, pain and suffering and economic loss.

6 133. As a direct and proximate result of one or more of these wrongful acts or
7 omissions of the AstraZeneca Defendants, or some or any one of them, Plaintiff suffered
8 profound injuries which are permanent and continuing in nature; required and will require
9 medical treatment and hospitalization; have become and will become liable for medical and
10 hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary
11 activities and duties and have and will continue to experience mental and physical pain and
12 suffering, disability and loss of enjoyment of life, all of which damages will continue in the
13 future.
14

15
16 **WHEREFORE**, Plaintiff demands judgment against each of the AstraZeneca Defendants
17 individually, jointly and/or severally for all such compensatory, statutory and punitive damages
18 available under applicable law, together with interest, costs of suit, attorneys' fees and all such
19 other relief as the Court deems proper.
20

21
22 **COUNT IX**
CONCEALMENT, SUPPRESSION, OR OMISSION OF MATERIAL FACTS

23 134. Plaintiff hereby adopts and incorporates by reference all preceding paragraphs as if
24 fully set forth herein and further alleges as follows:

25 135. The AstraZeneca Defendants omitted, suppressed, or concealed material facts
26 concerning the dangers and risks associated with the use of their drugs, including but not limited
27 to the risks of diabetes mellitus and other injuries. Further, the AstraZeneca Defendants
28

1 purposely downplayed and understated the serious nature of the risks associated with use of their
2 drugs in order to increase the sales of those drugs.

3 136. The AstraZeneca Defendants knew or should have known (and would have known
4 had appropriate testing been done) that use of their drugs caused serious and potentially life-
5 threatening side effects.
6

7 137. The AstraZeneca Defendants engaged in calculated silence despite their
8 knowledge of the growing public acceptance of misinformation and misrepresentations regarding
9 both the safety and efficacy of their drugs and did so because the prospect of significant future
10 profits caused them to ignore concerns regarding health and safety issues, all to the significant
11 detriment of the public, including the Plaintiff.
12

13 138. Many safer and less expensive anti-psychotics were available to patients being
14 treated with the AstraZeneca Defendants' drugs.

15 139. The AstraZeneca Defendants purposefully downplayed the side effects or provided
16 misinformation about adverse reactions and potential harms from their drugs, and succeeded in
17 persuading large segments of the relevant consumer market to request their drugs and large
18 segments of the medical community to prescribe their drugs, despite both the lack of efficacy and
19 the presence of significant dangers, as set forth herein.
20

21 140. The AstraZeneca Defendants had a post-manufacturing and continuing duty to
22 warn, which arose when they knew, or with reasonable care should have known, that their drugs
23 were injurious or fatal.

24 141. The AstraZeneca Defendants omitted, suppressed, or concealed material facts
25 concerning the dangers and risks associated with the use of their drugs, including but not limited
26 to the risks of death, disease and other health problems associated with the use of their drugs.
27 The AstraZeneca Defendants have purposely downplayed and/or understated the serious nature of
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1 the risks associated with the use of their drugs and have implicitly encouraged the use of these
2 drugs despite knowledge of the dangerous side effects that their drugs presents to the patient
3 population.

4 142. The AstraZeneca Defendants purposefully and knowingly promoted their drugs for
5 “off label” uses beyond the scope of the FDA approved uses and beyond those uses supported by
6 medical science.

7 143. The AstraZeneca Defendants unlawfully provided financial incentives to
8 physicians and others to prescribe and approve “off label” uses.

9 144. The AstraZeneca Defendants knew or should have known, and would have known
10 had appropriate testing been done, that the use of their drugs caused the serious and potentially
11 life threatening side effects.

12 145. The AstraZeneca Defendants’ actions as set forth herein constitute knowing
13 omission, suppression or concealment of material facts, made with the intent that others would
14 rely upon such concealment, suppression or omission, in connection with the marketing, sale and
15 use of their drugs.

16 146. In fact, the Plaintiff directly and/or through prescribing physicians was induced by
17 the AstraZeneca Defendants’ omissions and suppression and concealment of facts to use
18 AstraZeneca Defendants’ drugs.

19 147. As a direct and proximate result of the Plaintiff’s ingestion of AstraZeneca
20 Defendants’ drugs caused by the aforesaid acts and failures to act by the AstraZeneca Defendants,
21 Plaintiff suffered damages including but not limited to past, present and future pain and suffering,
22 serious physical injuries, loss of enjoyment of life, past and future medical expenses, and past
23 and/or future lost wages.

24 148. The AstraZeneca Defendants’ conduct is outrageous because of reckless
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1 indifference to the health and safety of Plaintiff and to the public so as to justify an award of
2 punitive damages.

3 **WHEREFORE**, Plaintiff demands judgment against the AstraZeneca Defendants for
4 damages for pain and suffering, loss of enjoyment of life, past and future medical expenses, past
5 and future lost wages, and punitive damages, together with interest from the date of injury and
6 costs.
7

8 **COUNT X**
9 **UNJUST ENRICHMENT**

10 149. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if
11 fully set forth herein.

12 150. Defendant has been unjustly enriched in the amount of the profits they have earned
13 as a result of Defendant's conduct as alleged herein.

14 151. Defendant has been unjustly enriched at the expense of and to the detriment of the
15 Plaintiff.

16 152. As a direct and proximate cause of Defendants conduct, the Plaintiff demands
17 judgment in her favor and against AstraZeneca in a sum in excess of \$75,000.00; for costs herein
18 incurred; attorneys fees; for such other and further relief as this Court deems just and proper.
19

20 **WHEREFORE**, Plaintiff demands judgment against the AstraZeneca Defendants for
21 damages for pain and suffering, loss of enjoyment of life, past and future medical expenses, past
22 and future lost wages, and punitive damages, together with interest from the date of injury and
23 costs.
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25 Dated: May 29, 2008
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1
2 Respectfully submitted,

3 THE MILLER FIRM, LLC

4
5 By: 
6 David C. Andersen, CA Bar No. 194095


7 THE MILLER FIRM, LLC
8 108 Railroad Avenue
9 Orange, VA 22960
10 Telephone: (540) 672-4224
11 Facsimile: (540) 672-3055

12 Attorney for Plaintiff

13
14 **DEMAND FOR JURY TRIAL**

15 Demand is hereby made for a trial by jury.

16
17
18 THE MILLER FIRM, LLC

19 By: 
20 David C. Andersen, CA Bar No. 194095

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